Title of Study: Practices of Vitamin D Supplementation leading to Vitamin D toxicity: Experience from a Tertiary care center of a Low Middle Income Country

Manuscript type: Original article

Date of Document: 2nd November 2019

NCT Number: NCT05139576

VERBAL INFORMED CONSENT (PHONE INTERVIEW)

Study ID ---------------------- Date of contact: ____/____/____

Asalam-o-Allaikum

I am Dr Siraj Muneer calling from The Aga Khan University. I am calling regarding a study which is being conducted by us. We are conducting this study to determine the frequency of hypervitaminosis and vitamin D toxicity in subjects being tested at the clinical laboratory of AKU and assess the use of supplementation as a reason of high vitamin D levels.

Do you have a few minutes to discuss the study?

You have been invited to participate in this study because your vitamin D test results performed at clinical laboratory AKU are high. In this study we will ask you few questions via telephone. We will collect specific details about your clinical history, including demographics, biochemical details, drug or supplementation history of calcium and vitamin D. The survey will take approximately 10-15 minutes of your time.

Being in this study is completely voluntary. Your decision whether to participate will not affect your current or future relationship with us or anyone else at the Aga Khan University.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time.

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

There may be no direct benefit to you also. However, the results of this study will help in increasing our understanding about prevalence and determinants of hypervitaminosis and vitamin D toxicity and may act as a database for future work.
Any information you provide will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Nobody except principal investigator and the immediate research team will have an access to it. Study findings may be published, but you will not be individually identifiable in these publications. If you wish, we can share the study findings with you.

This study has been approved by The Aga Khan University Ethics Review Committee and will be conducted in accordance with the ethical principles.

Do you have any questions about what was just mentioned? In case of further queries you may contact Dr. Siraj Muneer on following number 021-34861918 from 9 am to 5 pm (Monday to Friday).

Do you agree to participate in this study?

Name of Subject:

____________________________________________________

Person Obtaining Consent

I have read this form to the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject’s satisfaction. In my judgment, the subject has demonstrated comprehension of the information. The subject has provided oral consent to participate in this study.

Name and designation of Person obtaining Consent:

___________________________________________________________________________

Signature of Person obtaining Consent:

___________________________________________________________________________

Name and designation of Witness:
Signature of Witness

________________________________________

Date: _________________________________